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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
RAMIREZ, D	
ART UNIT	**PAPER NUMBER**
1652	8

DATE MAILED: 09/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/784,340	Applicant(s) WEI ET AL.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 August 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9,13 and 24-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *25 and 26* is/are allowed.

6)☒ Claim(s) *4,8,9,13,24 and 27-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 February 2001* is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Status of Application

Claims 4, 8, 9, 13 and 24-29 are pending.

Applicant's election of Group I with traverse, cancellation of claims 1-3, 5-7, 10-12 and 14-23, amendment of claims 4, 8 and 13, addition of claims 24-29, and receipt of a Statement Regarding Duty of Disclose Information Material to Patentability under 37 CFR 1.56 (a) and (b) in Paper No. 7, filed on 08/20/2001 is acknowledged.

Applicant's arguments filed on 8/1/2001, Paper No. 7, to include claim 13 in the elected group have been fully considered. The argument that the examination of this claim would not unduly burden the Examiner is deemed to be persuasive to overcome the restriction previously applied. Claim 13, drawn to a method for detecting a nucleic acid of claim 4, has been rejoined for examination.

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Isolated nucleic acid molecules encoding human drug-metabolizing proteins.

2. The specification is objected for not complying with sequence rules. Applicant is required to insert sequence identifiers in front of sequences referred to in the specification. See particularly 37 CFR 1.821(d). Applicant is requested to make the appropriate changes.

3. The specification is objected for discrepancies between the cDNA of SEQ ID NO: 1 and the genomic DNA of SEQ ID NO: 3. Several mismatches were found between the cDNA of

SEQ ID NO: 1 and the corresponding exons of the genomic DNA of SEQ ID NO: 3. A copy of the alignment is attached to this action.

4. The drawings have been reviewed by a draftsperson and are objected under 37 CFR 1.84. See attached Notice of Draftsperson's Patent Drawing Review.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 24 is indefinite in the recitation of "process for producing a polypeptide comprising culturing the host cell of claim 9" because it is unclear from the claim as written as to the identity of the polypeptide being produced. The host cell of claim 9 is capable of producing a large number of polypeptides, both native and recombinant. It is suggested that Applicants clearly define their intended polypeptide.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4, 8-9, 13, 9, 24, 27-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

8. Claim 4 (a) (claims 8-9, 13, 9, 24, 27-29 dependent thereon) is directed to a genus of DNA molecules encoding a protein comprising the amino acid sequence of SEQ ID NO: 2. The specification, while being enabling for the nucleic acid molecule encoding the amino acid sequence of SEQ ID NO: 2, it does not reasonably provide enablement for every nucleotide sequence that encodes a protein comprising the amino acid sequence of SEQ ID NO: 2. The specification discloses that the isolated nucleic acid molecule can include the sequence encoding the protein of SEQ ID NO: 2, the sequence encoding the mature peptide and additional coding and non-coding sequences such as (1) a leader or secretory sequence, (2) introns, (3) sequences needed for transcription, mRNA processing, ribosome binding and mRNA stability, and (3) marker sequences for peptides used in purification. The specification does not disclose any specific coding or non-coding sequences that could be part of the nucleic acid molecule encoding a protein comprising the amino acid sequence of SEQ ID NO: 2. While some of these additional coding and non-coding sequences are known in the art, there are many sequences that can be fused to the nucleic acid molecule of claim 4 (a) with functions and/or uses that have not been disclosed. Thus, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim.

9. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

10. Claim 13 is drawn to a method for detecting the molecule of claim 4 by using an oligonucleotide of at least 20 contiguous nucleotides that hybridizes to the nucleotide molecule of claim 4 under stringent conditions. It is known in the art that there is a direct relationship between oligonucleotide probe size and specificity for the target sequence (see Sambrook and Russell, Volume 2, page10.4, 2001), therefore an oligonucleotide of 20 contiguous nucleotides directed towards a large target sequence such as the nucleic acid molecule of claim 4 (c) and (d) (SEQ ID NO: 3, 21000 nucleotides) may result in the detection of other molecules besides the nucleic acid molecule of claim 4 (false positives). The specification discloses the conditions for hybridization and washing but it does not contain any disclosure of how to distinguish nonspecific hybridization from true positives which is needed to allow one skill in the art to properly use the claimed method. Therefore, Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 13 is rejected under 102 (b) as being anticipated over Jin et al. (Biochem. Biophys. Res. Commun. 194:496-503, 1993). Claim 13 is drawn to a method for detecting the nucleotide molecule of claim 4 using an oligonucleotide comprising at least 20 contiguous nucleotides that hybridizes to said molecule under stringent conditions. Jin et al. teaches a method for the screening of a cDNA library prepared from the mRNA of a single human liver that resulted in the isolation of two members of the human liver UDP-glucuronosyltransferase 2B subfamily (page 497, Materials and Methods section). Their method uses cDNA encoding a phenobarbital-inducible form of rat liver UDP-glucuronosyltransferase disclosed by Mackenzie (J. Biol. Chem. 261:6119-6125, 1996; TrEMBL accession number A42233, June 1992) as a probe in a hybridization assay. This rat liver UDP-glucuronosyltransferase has several fragments of at least 20 contiguous nucleotides with 100% homology to the nucleic acid molecule encoding the polypeptide of SEQ ID NO: 2 (see alignment and Figure 1, page 6121 of Mackenzie). The method of Jin et al. can detect the nucleic acid of claim 4, therefore, anticipates claim 13 as written.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jin et al. (Biochem. Biophys. Res. Commun. 194:496-503, 1993; TrEMBL accession number O75614,

November 1998). Claim 13 is drawn to a method for detecting the nucleic acid molecule of claim 4 using an oligonucleotide of at least 20 contiguous nucleotides that hybridizes to said molecule under stringent conditions.

Jin et al. teaches the cloning and expression of two members of the human liver UDP-glucuronosyltransferase 2B subfamily. One of these proteins (TrEMBL accession number O75614) has several fragments of at least 20 contiguous nucleotides with 100% homology to the nucleic acid molecule encoding the polypeptide of SEQ ID NO: 2 (see alignment and Figure 1, page 499 of Jin et al.). Jin et al. also teaches a method for screening of a cDNA library prepared from the mRNA of a single human liver using a hybridization assay. Jin et al. does not teach the use of the hybridization assay to detect the nucleic acid molecule of claim 4.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to use the nucleic acid molecule of Jin et al., or a fragment thereof, as a probe to use in the hybridization method also described by Jin et al. to detect the nucleic acid molecule of claim 4 in a sample. One would have been motivated to use the nucleic acid molecule disclosed by Jin et al, or a fragment thereof, in a hybridization assay because said nucleic acid molecule can potentially detect other nucleic acid fragments encoding human UDP-glucuronosyltransferases, which are useful biocatalysts . One would have a reasonable expectation of success because Jin et al. were able to successfully isolate two UDP-glucuronosyltransferases using the hybridization method with a cDNA probe encoding a rat liver UDP- glucuronosyltransferase (page 497, Materials and Methods section). Therefore, claim 13, drawn to a method for detecting the nucleic acid molecule of claim 4 using an oligonucleotide of at least 20 contiguous nucleotides

that hybridizes to said molecule under stringent conditions, would have been obvious to one of ordinary skill in the art.

Allowable Subject Matter

13. Claims 25-26 are allowed.

14. The following is an examiner's statement of reasons for allowance. The nucleic acid molecules of claims 25 and 26 are free of the prior art. Further, the prior art does not teach or suggest preparing the claimed nucleic acid sequences specifically, therefore said sequences are new and non-obvious.

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (703) 308-3804. Any inquiry of a

general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
September 7, 2001

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